UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,968	02/13/2002	Heinrich Wieland	38891.00100	6225

38647 7590 03/31/2010

MILBANK, TWEED, HADLEY & MCCLOY LLP
INTERNATIONAL SQUARE BUILDING
1850 K STRET, N.W., SUITE 1100
WASHINGTON, DC 20006

EXAMINER	
HANLEY, SUSAN MARIE	
ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
03/31/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/049,968	WIELAND ET AL.	
	Examiner	Art Unit	
	SUSAN HANLEY	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 January 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *54 and 56-71* is/are pending in the application.

4a) Of the above claim(s) *70 and 71* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *54 and 56-69* is/are rejected.

7)☒ Claim(s) *56* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments, filed 1/6/2010 have been fully considered regarding previous rejections have been fully considered and they are fully persuasive. Rejections and/or objection not reiterated from previous Office actions are hereby withdrawn. The following rejections and objections are newly applied. They constitute the complete set presently being applied to the instant application.

Claims 54 and 56-69 are under examination. Claims 70 and 71 stand withdrawn.

Claim Objections

Claim 56 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 54 is drawn to a method of treatment comprising administering a composition that inhibits aromatase to skin of an individual. Thus, these inhibitors are anti-estrogen compounds.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 54 and 56-69 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are rejected because the inclusion of the phrases "identifying a subject suffering from a collagen deficient condition" and "to a subject in an amount sufficient to alleviate at least one symptom of said collagen deficient condition" are New Matter. Neither the specification nor the claims as filed disclose these limitations.

Claims 54 and 56-69 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

To be enabling, the specification of the patent application must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. *In re Wright,* 999 F.2d 1557, 1561 (Fed. Cir. 1993). Explaining what is meant by "undue experimentation," the Federal Circuit has stated that:

> The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPG v. Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996).[1]

[1]As pointed out by the court in In re Angstadt, 537 F.2d 498 at 504 (CCPA 1976), the key word is "undue", not "experimentation".

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by *In re Wands',* 8 USPQ2d 1400 (CAFC 1988) at 1404 wherein, citing *Exparte Forman,* 230 USPQ 546 (Bd. Apls. 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,
2) the amount of direction or guidance provided,
3) the presence or absence of working examples,
4) the nature of the invention,
5) the state of the prior art,
6) the relative skill of those in the art,
7) the predictability of those in the art,
8) the breadth of the claims.

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. In re Fisher, 57 CCPA 1099, 1108,427 F.2d 833,839, 166 USPQ 18, 24 (1970). Keeping that in mind, the Wands" factors are relevant to the instant fact situation for the following reasons:

1. The nature of the invention, state and predictability of the art, and relative skill of those in the art

The invention relates to a method for stabilizing, increasing or restoring collagen by identifying a collagen deficient condition selected from the group consisting of wrinkles, strias, atony of the skin or sun exposure to the skin by topically administering an aromatase inhibitor in an amount sufficient to alleviate at least one symptom of said collagen deficient condition. The composition got the method can further comprise a 5-alpha-reductase inhibitor and an anti-estrogen. The aromatase inhibitor can be a steroid, a sterol, or a sterol isolated from soya glycines which can be oxidized.

The relative skill of those in the art is high, generally that of a medical doctor or a PhD biochemist.

That factor is outweighed, however, by the unpredictable nature of the art. It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved", and physiological activity is generally considered to be an unpredictable factor. See *In re Fisher,* 166 USPQ 18, at 24 (In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.), *Nationwide Chemical Corporation, et al. v. Wright, et al.,* 192 USPQ 95 (one skilled in chemical and biological arts cannot always reasonably predict how different chemical compounds and elements might behave under varying circumstances), *Ex parte Sudilovsky* 21 USPQ2d 1702 (Appellant's invention concerns pharmaceutical activity. Because there is no evidence of record of analogous activity for similar compounds, the art is relatively unpredictable) *In re Wright* 27 USPQ2d 1510 (the physiological activity of RNA viruses was sufficiently unpredictable that success in developing specific avian recombinant virus vaccine was uncertain).

The prior art shows that loss of estrogen decreases collagen content in the skin and that augmentation of the skin with collagen increases collagen content. For example, Affinto et al. discloses that a study to evaluate the effect of aging and postmenopausal hypoestrogenism on skin collagen content. It was shown that in postmenopausal patients, there was a statistically significant decrease of percentage of

skin collagen type I, type III and type III/type I ratio in comparison to pre-menopausal women. The observation correlated with chronological age. Affinito et al. conclude that the data suggests that the decrease of skin collagen is an estrogen-related phenomenon (abstract, page 241, right col., under "Results", Figs 1-4 and page 246, right col.)

Brincat et al. evaluated skin collagen changes in post-menopausal women receiving oestradiol (estradiol) gel topically for one year. Skin biopsies of the abdomen and the thigh demonstrated that abdominal collagen significantly increased while the increase in thigh collagen was not statistically significant (abstract and Fig. 1-3).

Varila et al. examined the effect of topical estradiol on skin collagen and elastin. Varila et al. observed that the application of topical estradiol increases the amount of skin collagen (abstract and "Results", page 986). Varila notes that the mechanical properties of the skin such as tensile strength are largely attributed to the collagen component (p. 988, right col. fourth paragraph).

Aromatase is the enzyme responsible for the biosynthesis of estrogens. Inhibition of aromatase will inhibit the formation of estrogens. The prior art discloses that estradiol, a product of aromatase catalysis of testosterone supports the formation of collagen in the skin. Hence, the skilled artisan would reasonably expect that inhibition of aromatase would lead to a decrease in estrogen and result in a decrease in the amount of collagen in the skin, thus leading to wrinkles, etc. Hence, there is no way for one skill in the art to know, a priori, if a given inhibitor of aromatase can restore, increase or stabilize the

amount of collagen in the skin of an individual a reasonable expectation of results. Thus, the state of the prior art does not support the broad scope of the above claims.

Furthermore, the isolation of natural products is complex. A natural product contains a plethora of bioactive compounds of widely different structures and functions. Isolation of natural products is painstaking due to the difficulty in the separation of the multitude and structural variety of compounds contained in a natural product.

2. The breadth of the claims

The claims are broad insofar as they disclose a method for stabilizing, increasing or restoring collagen in a subject suffering from wrinkles, strias, atony of the skin and sun exposure to the skin by the application of an aromatase inhibitor such as sterols isolated from soya glycines that can be oxidized.

3. The amount of direction or guidance provided and the presence or absence of working examples

The specification alleges that collagen and therefore skin tightness can be positively influenced in collagen-containing body parts by using a substance which is capable of inhibiting the production and/or the effect of estrogens (page 6, lines 14-21). The specification discloses that by means of biopsies it was found that the proportion of collagen fibers increased (page 7, lines9-11). The specification does not actually disclose what substance was applied and where it was applied to produce this outcome. A comparison of Figs. 1 and 2 allegedly shows that the proportion of the collagen fibers increases after application of (presumably) an inhibitor of aromatase. There is no description of what aspect of collagen the pictures represent. It is difficult to tell from the

pictures what aspect of collagen is being shown. The specification does not explain what the figures physically represent. If is difficult to tell from the pictures if there is an increase or decrease in the proportion of collagen fibers.

The specification does not make a reasonable correlation between the inhibition of aromatase activity and collagen synthesis. There is no data to support the concept that inhibition of aromatase and thus the decrease in the amount of estrogen leads to an increase in collagen fibers.

The specification provides two examples wherein wrinkles and strias were treated with oxidized soya glycines. The specification reports that there was an improvement in the appearance of the wrinkles and strias of the patient after the application of oxidized soya glycines. However, the specification does not correlate this alleviation of wrinkles or strias with an increase of collagen fiber or the inhibition of aromatase. It is unclear if sterols from soya glycines that can be oxidized inhibit aromatase.

Furthermore, the claims are drawn to the application of sterol isolated from soya glycines. The disclosure states that these inhibitors of aromatase can be derived from soy bean oil, soy bean extract or soya sterol by generally using typical separation methods such as HPLC. It is also disclosed that the effect of the oxidation of soya glycines increases the effect on collagen synthesis (p. 13-14).

The specification does not teach how to isolate (make) the sterols from soya glycines. In the case of soy bean oil, it is unclear how one treats soy bean oil to isolate the sterols. Is raw oil injected into an HPLC instrument to isolate the sterols? Are there

some intermediate steps to treat the soy bean oil to isolate the alleged aromatase inhibitors? For a soy bean extract, there is no disclosure relating how the sterols are extract from soy beans to make an extract. Is it an aqueous or organic extraction? The nature of the extraction will govern what will be in the extract. Are there intermediate steps to isolate the sterol? The specification is confusing regarding the isolation of aromatase inhibitors from soya sterole. Does this mean that the sterol is already provided? In any of these cases, it is unclear how the isolation of soy sterols relates to aromatase inhibitors. Are all sterols isolated from soy aromatase inhibitors?

Furthermore, the nature of the oxidation of soya glycines is unclear. The specification cites two references regarding methods to carry out this process. An enzymatic method reported by Fujimoto is directed to the microbial degradation of the phytosterol chain of specific steroids. 3-oxo-24-ethylchoest-4-en-26-oic acid was converted into 3-oxochol-4-en-24-oic acid and androst-4-ene-3,17-dione. These conversions do not appear to be related to oxidation. The conversion to the dione suggests a reduction. Fujimoto discloses that they were unable to obtain workable quantities of the degradation product corresponding to 26-hydroxy-24-ethylcholest-4-ene. Thus, it is unclear if the microbial process results in any type of oxidation or if it is applicable to any possible steroid.

Regarding the chemical method reported by Welzel et al., the degradation of the steroid chain provides a ketone, so this is an oxidation. However, the specification fails to disclose how this relates to the structures of the unknown sterols allegedly isolated from soy glycines. That is, since the structures of the sterols isolated from soya glycines

are unknown, the skilled artisan would not know what compounds would be obtained from the treatment of said compounds by the method of Welzel et al. and if the resulting compounds would necessarily be inhibitors of aromatase.

The specification discloses that the topical application of oxidized soya glycines provides a positive effect on the appearance of wrinkles and strias. However, there is no disclosure that correlates the improvement to an increase in collagen fibers or if the inhibition of aromatase is responsible for the effect. Furthermore, the specification discloses the application of oxidized soy glycines to skin. It is unclear from the disclosure if the substance applied to the skin was soy bean oil or an extract thereof that was subjected to one of the disclosed degradation reactions or if isolated oxidized sterol were applied to the skin for the positive effect on wrinkles and strias.

Thus, the specification does not support the concept that inhibition of aromatase leads to a decrease in estrogens that causes an increase, restoration or stabilization of collagen in the skin. Furthermore, the specification does not teach how to isolate (make) sterols that inhibit aromatase from soy glycines or oxidized soya glycines.

4. The quantity of experimentation necessary

Because of the known unpredictability of the art *supra* and in the absence of experimental evidence commensurate in scope with the claims, the skilled artisan would not accept the assertion that one could be predictably stabilize, restore or increase collagen in skin by the application of aromatase inhibitor or obtain sterols from soya glycines or oxidized soya glycines that inhibit aromatase as inferred in the claims and contemplated by the specification. Genentech Inc. vs. Nova Nordisk states, "[A] patent

is not a hunting license. It is not a reward for a search but a compensation for its successful conclusion and 'patent protection' is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" (42 USPQ 2d 1001, Fed. Circuit 1997).

To practice the invention of the instant claims required undue experimentation due to unpredictability and the lack of direction from Applicants regarding the restoration, increase or stabilization of collagen by decreasing the estrogen content in the skin by the inhibition of aromatase as well as the isolation sterol from soya glycines that inhibit aromatase. In light of the above discussion, the instant claims do not comply with the enablement requirement of 35 U.S.C. § 112, first paragraph, since to practice the claimed invention a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success.

Claims 54, 59, 60 and 62-64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 62 is rejected insofar as it reads on sterols isolated from soya glycines that can be oxidized. Claim 59 is interpreted to mean that the aromatase inhibitor in the method of claim 54 is also an inhibitor of the production and/or the effect of dihydroxytestosterone since the aromatase inhibitor is the only active substance named in claim 54. Claim 60 is

interpreted to mean that the aromatase inhibitor in the method of claim 54 is also a 5-alpha reductase inhibitor since the aromatase inhibitor is the only active substance named in claim 54.

The claims are drawn to a method for stabilizing, increasing or resorting collagen in skin due to wrinkles, strias, sun exposure and atony of the skin by the administration of an aromatase inhibitor including sterols from soya glycines that can be oxidized or the administration of aromatase inhibitors that additionally inhibit 5-alpaha-reductase and the production and/or effect of dihydroxytestosterone. The extremely broad genus terms: sterols from soya glycines or oxidized soya glycines, an inhibitor of aromatase and 5-alpha-reductase and an aromatase inhibitor that inhibits the production and/or effect of dihydroxytestosterone do not have sufficient description in the specification, nor are a representative number of compounds described within any one of these genera to demonstrate that applicant was in possession at the time of filing of any one of these genus terms.

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989)("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents" of the University of California v. Eli Lilly & Co.* the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers,* 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe,* 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents" of the University of California v. Eli Lilly &* Co., 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163. The MPEP does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitutes a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli,* the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli,* 872, F.2d at 1012, 10 USPQ2d at 1618.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163. While all of the factors have been considered, a sufficient amount for *a prima facie* case are discussed below.

(1) Level of skill and knowledge in the art:

The level of skill and knowledge in the art is high.

(2) Partial structure:

Regarding sterol isolation from soya glycines, the specification refers only to sterols isolated from soya glycines or oxidized soya glycines that can inhibit aromatase. The specification doe not provide a partial structure of any sterols isolated from said sources. It is only known that they are steroids with a hydroxy functionality.

The specification does not provide partial structures of compounds that inhibit aromatase that also have the ability to inhibit 5-alpha reductase or inhibit the production and/or effect of dihydroxytestosterone.

(3) Physical and/or chemical properties and (4) Functional characteristics:

Applicant has not set forth the physical and/or chemical properties and functional characteristics for sterols isolated from soya glycines that can be oxidized that are inhibitors of aromatase. The specification does not disclose the relationship between the structure of a sterol isolated from soy glycines that can be oxidized and how this structure leads to the inhibition of aromatase and the increase, restoration or stabilization of collagen .

Likewise, the specification does not disclose the relationship between the structure of an inhibitor that has the dual ability to inhibit aromatase and 5-alpha-reductase or the production and/or the effect of dihydroxytestosterone.

(5) Method of making the claimed invention:

The specification does not teach how to isolate (make) the sterols from soya glycines. The specification teaches that soya glycine derived aromatase inhibitors can be obtained from "glycine soya" (soy bean oil, soy bean extract or soya sterole (p. 13). In the case of soy bean oil, it is unclear how one treats soy bean oil to isolate the sterols. If the raw oil itself injected into an HPLC instrument to isolate the sterols? Are there some intermediate steps to treat the soy bean oil to isolate the alleged aromatase inhibitors? For a soy bean extract, there is no disclosure relating how the sterols are extract from soy beans to make an extract. Is it an aqueous or organic extraction? The nature of the extraction will govern what will be in the extract. Are there intermediate steps to isolate the sterol? The specification is confusing regarding the isolation of

aromatase inhibitors from soya sterole. Does this mean that the sterol is already provided? In any of these cases, it is unclear how the isolation of soy sterols relates to aromatase inhibitors. Are all sterol isolated from soy aromatase inhibitors?

Furthermore, the nature of the oxidation of soya glycines is unclear. The specification cites two references regarding the method to carry out this process. An enzymatic method reported by Fujimoto is directed to the microbial degradation of the phytosterol chain of specific steroids. 3-oxo-24-ethylchoest-4-en-26-oic acid was converted into 3-oxochol-4-en-24-oic acid and androst-4-ene-3,17-dione. These conversions do not appear to be realted to oxidation. The conversion to the dione suggests a reduction. Fujimoto discloses that they were unable to obtain workable quantities of the degradation product corresponding to 26-hydroxy-24-ethylcholest-4-ene. Thus, it is unclear if the microbial process results in any type of oxidation or if it is applicable to any possible steroid.

Regarding the chemical method reported by Welzel et al., the degradation of the steroid chain provides a ketone, so this is an oxidation. However, the specification fails to disclose how this relates to the structures of the unknown sterols allegedly isolated from soy glycines. That is, since the structures of the sterols isolated from soya glycines are unknown, the skilled artisan would not know what compounds would be obtained from the treatment of said compounds by the method of Welzel et al. and if the resulting compounds would necessarily be inhibitors of aromatase.

The specification does not teach how to make compounds that inhbit aromatase or the production and/or the effect of dihydroxytestosterone.

As stated *supra,* the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that claims 54, 59, 60, 63 and 64 are broad and generic, with respect to all possible sterols isolated from soya glycines that can be oxidized or what compounds have the dual ability to inhibit aromatase as well as inhibit the production and/or the effect of dihydroxytestosterone as encompassed by the claims. The possible structural variations are limitless. Although the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds. Moreover, the specification lacks sufficient variety of species to reflect this variance in the genus.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder,* 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

US 6,641,848 is cited to show the state of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN HANLEY whose telephone number is (571)272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sandra Saucier/
Primary Examiner, Art Unit 1651

/Susan Hanley/
Examiner, Art Unit 1651